DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 11, 2016

BECTON, DICKINSON AND COMPANY
PAUL SWIFT
ASSOCIATE MANAGER, REGULATORY AFFAIRS
7 LOVETON CIR., MC 694
SPARKS MD 21152

Re: K141810
Trade/Device Name: BD BACTEC Plus Anaerobic/F (plastic)
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial growth monitor
Regulatory Class: I
Product Code: MDB
Dated: November 5, 2014
Received: November 6, 2014

Dear Mr. Swift:

This letter corrects our substantially equivalent letter of December 10, 2014**.**

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 Parts 801 and 809); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809**]**), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K141810

Device Name
BD BACTEC™ Plus Anaerobic/F (plastic)

Indications for Use *(Describe)*

The BD BACTEC™ Plus Anaerobic/F medium is used in a qualitative procedure for the anaerobic culture and recovery of microorganisms (bacteria) from blood. The principal use of this medium is with the BD BACTEC fluorescent series instruments.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
7 LOVETON CIRCLE
SPARKS, MD 21152
Phone: 410-316-4905
Fax: 410-316-4188

CONTACT NAME: Paul Swift, RAC Associate Manager, Regulatory Affairs

DATE PREPARED: **October 30, 2014** (revised March 8, 2016)

DEVICE TRADE NAME: BD BACTEC™ Plus Anaerobic/F (plastic)

DEVICE COMMON NAME: Anaerobic blood culture medium

DEVICE CLASSIFICATION: 21 CFR§866.2560, Class I

PREDICATE DEVICE: BD BACTEC Plus Anaerobic/F medium (K954925)

INTENDED USE:
The BD BACTEC Plus Anaerobic/F medium is used in a qualitative procedure for the anaerobic culture and recovery of microorganisms (bacteria) from blood. The principal use of this medium is with the BD BACTEC fluorescent series instruments.

DEVICE DESCRIPTION:
The sample to be tested is inoculated into one or more vials which are inserted into the BD BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO_2 produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO_2 present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

DEVICE COMPARISON: The BD BACTEC Plus Anaerobic/F (plastic) medium differs from the BD BACTEC Plus Anaerobic/F (glass) medium in the following ways:

- The medium in the new device is contained in a multilayer polycarbonate/nylon/polycarbonate plastic bottle; whereas, the medium in the predicate device is contained in a glass bottle.

- The new device contains 2.6 g of sensor per bottle; whereas, the predicate device contains 1.75 g of sensor per bottle.
    - The volume of sensor has been adjusted for the plastic bottle to accommodate for differences in bottle geometry (thickness and shape) compared to the glass bottle.

- The indicator and red dye concentrations in the new device have been increased to yield signals that are equivalent to the glass bottle.
    - The bromocresol purple indicator (BCP) in the new device's sensor has been increased from a ratio of 1 mg per gram of sensor in the predicate device to a ratio of 2.5 mg per gram of sensor in the new device.
    - The radglo red dye in the new device's sensor has been increased from a ratio of 1.09 mg per gram of sensor in the predicate device to a ratio of 1.54 mg per gram of sensor in the new device.
    - The concentrations used in the plastic bottle accommodate for differences in overall sensor volume per bottle.

- A clear, inert adhesion promoter has been added to the new device's sensor to ensure adhesion of the sensor to the polycarbonate surface of the plastic bottle. The glass surface of the predicate device does not require an adhesion promoter.
    - The new device's sensor contains 13 mg per bottle of the adhesion promoter 3-glycidoxypropyl trimethoxysilane (GOP). This is not used in the predicate device.

- The new bottle weighs 20.9g compared to the predicate device bottle weight of 113g.

- The new device measures 5.0 inches high compared to the predicate device height of 5.6 inches.

- The new device contains 30 mL of soybean casein digest broth; whereas, the predicate device contains 25 mL of soybean casein digest broth.

The BD BACTEC Plus Anaerobic/F (plastic) medium is similar to the BD BACTEC Plus Anaerobic/F (glass) medium in the following ways:

 Both the new and predicate devices are used for the qualitative anaerobic culture and recovery of microorganisms from human blood. Both devices are intended to be used with the BD BACTEC fluorescent-series of blood culture instruments. The BD BACTEC fluorescent-series of blood culture instruments apply the same incubation and agitation parameters to both devices. The BD BACTEC fluorescent-series of blood culture instruments apply the same growth and detection algorithms to both devices. Both devices are incubated at 35° C (± 1.5° C) for a period of up to 120 hours. Both devices incorporate a sensor that detects increases in CO_2 within the bottle as a result of organism growth. Both devices require a sample volume of 3 – 10 mL of blood. Both devices incorporate resins for the adsorption of antimicrobials that may be present in clinical samples. Both devices utilize the same formulation of enriched soybean casein digest broth as the growth medium.

SUMMARY OF PERFORMANCE DATA

Analytical Studies:

Instrument Time to Detection

A total of 442 paired sets were positive in both the new and predicate devices. The median TTD difference between the paired positive sets was 4.62 minutes, favoring the new device. The data indicate that the effect of differences between the new and predicate devices on TTD under these test conditions was minimal and that the new device performs equivalently to the predicate device.

Percent Recovery

There was a significant difference in recovery between the BD BACTEC Plus Anaerobic/F blood culture medium contained in plastic bottles and the predicate device contained in glass bottles, favoring the new device contained in plastic vials. A total of 528 paired sets were evaluated in the Percent Recovery comparison. Of those, 442 paired sets were positive in both the new and predicate devices. The data indicate that the effect of differences between the new and predicate devices on percent recovery under these test conditions was detectable, with the new device detecting 12 more vials than the predicate device.

False Positive Rate

A total of 240 paired sets were used to execute this study. The 240 paired sets were comprised of 80 bottles from each of 3 lots. The paired sets were inoculated with fresh human blood at varying levels as specified by the test protocol and entered into the BACTEC blood culture instrument. It was expected that each bottle would be instrument-negative following the complete protocol (120 hours). There were no false positive bottles of the new device observed within the recommended usage range of blood volumes (3 to 10 mL).

False Negative Rate

A total of 146 paired sets were evaluated for the determination of the False Negative Rate of the new device. Additionally, there were 30 sets where only the predicate device detected and 67 sets where the new device only detected. All vials that did not detect were evaluated for false negativity via terminal subculture. Of these, sixteen (16) were false negative bottles (i.e., instrument-negative, subculture positive). Fourteen (14) false negative results were observed in the predicate device contained in the glass bottle. Two
(2) false negative results were observed in the modified device contained in the plastic bottle.

Antimicrobial Neutralization Capability

Eleven drugs representative of their classes were evaluated at the MIC level of selected strains to demonstrate equivalent performance of the new device to the predicate device. A total of 90 paired sets of medium were tested. The predicate device detected positive 87 times (96.67%) and the new device detected positive 86 times (95.56%). The drugs evaluated were: Ciprofloxacin, Cefazolin, Cefotaxime, Cefepime, Cefoxitin, Clindamycin, Gentamicin, Meropenem, Metronidazole, Piperacillin/Tazobactam and Vancomycin.

Reproducibility

The new device was evaluated for reproducibility across lots in terms of time to detection and recovery. There was a statistical difference in time to detection observed between a lot comparison; however differences were marginal with the mean and median difference being less than 1 hour.